

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-040-12n
=====

App number: 2000-103XRAB
Received: 2/09/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/10/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/08/00
End movement: 2/07/01
Begin release: 2/08/00
End release: 2/07/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085
=====

Initial Date

1. ☒ Assign Bp number and initial data entry [*ajd*] [2/10/2000]
2. ☒ Review by biotechnologist [*JK*] * [2/11/2000]
3. ☒ Letter of notification to State *Fed-ex* [*KLW*] [2/14/00] *
4. ☐ State response

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[]
Interstate	*Dest*	ND	*	*SCR	*	[]
Interstate	*Orig*	KS	*	*SCR	*	[]
Interstate	*Orig*	ND	*	*SCR	*	[]
Release	*	*ND	*	1*SCR	*	[]

5. ☐ Enter genes into database [] []
6. ☒ Letter of acknowledgement/denial/withdraw [*KLW*] [3/9/00] *
7. ☒ Enter final data into database [*KLW*] [3/10/00]

(b) (6), (b) (7)(C)

Asked *so can't
shu m
form.*

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-103XRAB

Permit Unit

February 08, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-040-12n

1. USDA Reference Number

2. Applicant Reference Number 2000-103XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

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Monsanto Reference ID

2000-103XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-103XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-103XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

KS

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

ND

(b) (4)

Cass County, ND, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2000-103XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

ND

(b) (4) Cass County, ND, (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
2000-103XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Cass County, ND, U.S.A, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C) U.S.A,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

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PHONE (314) 694-1000

<http://www.monsanto.com>

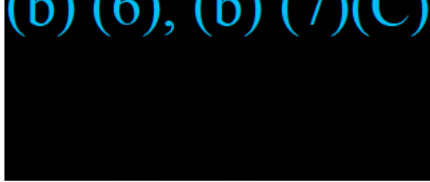
Monsanto Reference ID

2000-103XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 08, 2000

OR120018_BR_005090

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-103XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-12n

1. USDA Reference Number

2. Applicant Reference Number 2000-103XRAB

3. Applicant/Responsible Party

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636/737-7085

Email

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-103XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-103XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-103XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

ND

(b) (4)

Cass County, ND, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

ND

(b) (6), (b) (7)(C), (b) (4)

U.S.A,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (6), (b) (7)(C), (b) (4)

Sedgwick County, KS

(b) (6), (b) (7)(C), (b) (4)

USA

CBI-DELETED

Monsanto Reference ID
2000-103XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) KS (b) (6), (b) (7)(C), (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

ND

(b) (4)

Cass County, ND, (b) (4) U.S.A

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) ND, (b) (6), (b) (7)(C), (b) (4) U.S.A, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-103XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Cass County, ND, U.S.A, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) ND, (b) (6), (b) (7)(C), (b) (4) U.S.A, (b) (6), (b) (7)(C), (b) (4)

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-103XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 08, 2000

OR120018_BR_005101

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

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Monsanto Reference ID

2000-103XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 08, 2000

00-040-12n

1. USDA Reference Number

2. Applicant Reference Number 2000-103XRAB

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FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2000 - February 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-103XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-103XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-103XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

(b) (4)

Sedgwick County, KS (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS,

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

ND

(b) (4)

Cass County, ND (b) (4) J.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

ND,

(b) (6), (b) (7)(C), (b) (4)

J.S.A,

(b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (4)

Sedgwick County, KS, (b) (4) USA

CBI-DELETED

Monsanto Reference ID
2000-103XRAB

CONTACT: (b) (6), (b) (7)(C) KS, (b) (6), (b) (7)(C) USA, (b) (6), (b) (7)(C)

ND

(b) (4)

Cass County, ND (b) (4) .S.A

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) ND (b) (6), (b) (7)(C), (b) (4) U.S.A

CBI-DELETED

Monsanto Reference ID
2000-103XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Cass County, ND, U.S.A, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) ND (b) (6), (b) (7)(C), (b) (4) U.S.A. (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

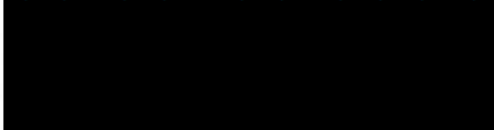
Monsanto Reference ID
2000-103XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63108
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
February 08, 2000

OR120018_BR_005108

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-12n	Applicant #:	2000-103XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005109

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 2000

Dear Mr. Nelson:

Enclosed is notification 00-040-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-12n	Applicant #:	2000-103XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005110



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281



February 10, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-040-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-12n	Applicant #:	2000-103XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

*State cannot evaluate
provided information.*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 2/24/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_005111



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 2000

Dear Mr. Nelson:

Enclosed is notification 00-040-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-040-12n	Applicant #:	2000-103XRAB
Received:	February 9, 2000	Effective:	March 10, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 2-16-00

State: ND

RptLoc01/R4



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FEB 16 2000

OR120018_BR_005112

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 10, 2000.

Interstate movement and Release
Notification no. 00-040-12n (2000-103XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-040-12n

OR120018_BR_005113

Confirmation Report-Memory Send

Time : Mar-09-00 02:46pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 812
Date : Mar-09 02:41pm
To : 916367377085
Document Pages : 01
Start time : Mar-09 02:41pm
End time : Mar-09 02:46pm
Pages sent : 01
Job number : 812

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 9, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 10, 2000.

Interstate movement and Release
Notification no. 00-040-12n (2000-103XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005114

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-041-03n
=====

App number: 2000-108XRAB
Received: 2/10/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/11/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/09/00
End movement: 2/08/01
Begin release: 2/09/00
End release: 2/08/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>aid</i>]	[2/10/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>//</i>]*	[2/11/2000]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[<i>KZAO</i>]	[2/14/00]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Release	*	*MT *	1*WR *

5. <input type="checkbox"/> Enter genes into database	[]	[]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KZAO</i>]	[2/28/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KZAO</i>]	[2/28/00]

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-108XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 09, 2000

00-041-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-108XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-108XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [REDACTED] (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1100 pounds of wheat seed to and from each shipment.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From:

MO

(b) (4)

Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C) MO, U.S.A, (b) (4), (b) (6), (b) (7)(C)

MT

(b) (4)

Cascade County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

MT

(b) (4) Cascade County, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-108XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (1)

MT

(b) (4), (b) (6), (b) (7)(C) Pondera County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-108XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 09, 2000

OR120018_BR_005127

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-108XRAB

February 09, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-041-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-108XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2000-108XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1100 pounds of wheat seed to and from each shipment.

ORIGIN:
MO, MT

DESTINATION:
MO, MT

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A., (b) (6), (b) (7)(C), (b) (4)

MO,

MT

(b) (4)

Cascade County, MT, (b) (4) USA

CONTACT

(b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CBI-DELETED

Monsanto Reference ID
2000-108XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) D.S.A. (b) (6), (b) (7)(C), (b) (4)

MT
(b) (4) Cascade County, MT, (b) (4) USA

CONTACT (b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

(b) (6), (b) (7)(C), (b) (4) Pondera County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

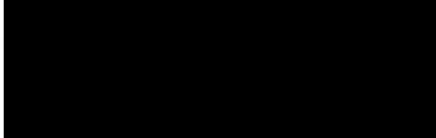
Monsanto Reference ID

2000-108XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2000

OR120018_BR_005142

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-108XRAB

February 09, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-041-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-108XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

Gene: CTP7-CP4 -- [CBI Deleted]

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

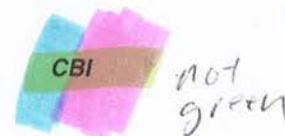
GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI



CBI

CBI

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1100 pounds of wheat seed to and from each shipment.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A

CONTACT:

REDACTED (b) (6), (b) (7)(C), (b) (4)

U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

MT

(b) (6), (b) (7)(C), (b) (4)

Cascade County, MT

(b) (6), (b) (7)(C), (b) (4)

USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

Great Falls, MT

(b) (6), (b) (7)(C), (b) (4)

SA

(b) (6), (b) (7)(C), (b) (4)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CBI-DELETED

Monsanto Reference ID
2000-108XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) U.S.A. (b) (6), (b) (7)(C), (b) (4)

MT
(b) (4) Cascade County, MT, (b) (4) USA

CONTACT (b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-108XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

(b) (6), (b) (7)(C), (b) (4) Pondera County, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>


Monsanto Reference ID

2000-108XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2000

OR120018_BR_005154

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-041-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-03n	Applicant #:	2000-108XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005155

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 10, 2000

Dear Dr. Gingery:

Enclosed is notification 00-041-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-03n	Applicant #:	2000-108XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005156



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-041-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	00-041-03n	Applicant #:	2000-108XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

B. Diane Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/17/00

State: MO

Rptloc01/R4

FEB 18 2000



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005157



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 10, 2000

Dear Dr. Gingery:

Enclosed is notification 00-041-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-03n	Applicant #:	2000-108XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/16/00

State: Montana

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_005158

FEB 16 2000

February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 11, 2000.

Interstate movement and Release
Notification no. 00-041-03n (2000-108XRAB)
Regulated article - Wheat
Destinations - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-041-03n

OR120018_BR_005159

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

August 10, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications, it was discovered there was an omitted line number. The following are the affected notifications.

USDA #	Monsanto #
00-041-03n	2000-108XRAB
00-041-06n	2000-111XRAB
00-041-04n	2000-109XRAB
00-059-02n	2000-181XRAB

I apologize for any inconvenience this may cause, please call me at 636/737-6032, if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric, Pierre, SD
G. Gingery, Montana Dept. of Agric, Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005160

MONSANTO

Food · Health · Hope



T. Wessels, Washington Dept. of Agric., Jefferson City, MO

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

OR120018_BR_005161

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-041-03n **Monsanto # 2000-108XRAB**

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Pondera

State
MT

Pondera County, MT - Site 1

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-041-03n Monsanto # 2000-108XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Pondera

State
MT

Pondera County, MT – Site 1

Planting Date: April 28, 2000

Harvest Date: August 23, 2000

Destruct Date: August 24, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT13, lines TA_S5450, TA_S317, TA_S621, TA_S635, TA_S1081, TA_S2520; PV-TXGT23, lines TA_S7535, 9215; PV TXGT17 line TA_S9240; PV-TXGT10 line 33391; PV-TXGT12 line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-041-03n Monsanto #2000-108XRAB

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147303362

County
Pondera

State
MT

Pondera County/MT (2147303362)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

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* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

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Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

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CBI-DELETED

2000 Wheat Field Test Report
USDA #00-041-03n Monsanto #2000-108XRAB

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147303362	Pondera	MT

Pondera County/MT (2147303362)

Planting Date: 04/28/2000

Harvest Date: 08/23/2000

Destruct Date: 08/24/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-041-04n
=====

App number: 2000-109XRAB
Received: 2/10/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/11/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/09/00
End movement: 2/08/01
Begin release: 2/09/00
End release: 2/08/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

=====
Initial Date
1. ☒ Assign Bp number and initial data entry [*aid*] [2/10/2000]
2. ☒ Review by biotechnologist [*if*] * [2/11/2000] *
3. ☒ Letter of notification to State *Fed-ex* [*KLW*] [2/14/00] *
4. ☐ State response

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Dest*	WA	*	*WR	*	[]
Interstate	*Orig*	MO	*	*SCR	*	[]
Interstate	*Orig*	WA	*	*WR	*	[]
Release	*	WA	*	1*WR	*	[]

5. ☐ Enter genes into database [] []
6. ☒ Letter of acknowledgement/denial/withdraw [*KLW*] [2/28/00] *
7. ☒ Enter final data into database [*KLW*] [2/28/00]

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-109XRAB

Permit Unit

February 09, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-041-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-109XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-109XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVa/12 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)
actin 1 gene.] - CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

designation of transformed line:

TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3'

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [REDACTED] (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

Promoter: CMP3/15-3 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [REDACTED]

(b) (4) (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-109XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:
MO, WA

DESTINATION:
MO, WA

Ship From:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

MO,

WA

(b) (4)

Walla Walla County, WA (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

WA,

Ship To:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

CONFIDENTIAL

Monsanto Reference ID
2000-109XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA,
(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
2000-109XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Walla Walla County, WA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-109XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 09, 2000

OR120018_BR_005183

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-109XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 09, 2000

00-041-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-109XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:
MO, WA

DESTINATION:
MO, WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) U.S.A,

WA

(b) (4)

Walla Walla County, WA (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4) WA,
(b) (6), (b) (7)(C), (b) (4)

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) U.S., (b) (6), (b) (7)(C), (b) (4)

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) WA,
(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-109XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Walla Walla County, WA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-109XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 09, 2000

OR120018_BR_005198

MONSANTO

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MONSANTO COMPANY

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Monsanto Reference ID

2000-109XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 09, 2000

00-041-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-109XRAB

3. Applicant/Responsible Party

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]



Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

(b) (4)

t. Louis County, MO (b) (4), U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

St. Louis, MO,

WA

(b) (4)

Walla Walla County, WA (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

WA,

Ship To:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A.,

(b) (6), (b) (7)(C), (b) (4)

St. Louis, MO,

WA

(b) (4)

Walla Walla County, WA, (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

WA,

CBI-DELETED

Monsanto Reference ID

2000-109XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Walla Walla County, WA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4)

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CBI-DELETED

Monsanto Reference ID

2000-109XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2000

OR120018_BR_005210

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-041-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-04n	Applicant #:	2000-109XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005211

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 2000

Dear Mr. Wessels:

Enclosed is notification 00-041-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-04n	Applicant #:	2000-109XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005212



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-041-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-04n	Applicant #:	2000-109XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date: 2/17/00

State: MO

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_005213

FEB 18 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 2000

Dear Mr. Wessels:

Enclosed is notification 00-041-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-04n	Applicant #:	2000-109XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/15/00

State: WA

Rptloc01/R4



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FEB 15 2000

OR120018_BR_005214

February 28, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 11, 2000.

Interstate movement and Release
Notification no. 00-041-04n (2000-109XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA

File number 00-041-04n

OR120018_BR_005215

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

August 10, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications, it was discovered there was an omitted line number. The following are the affected notifications.

USDA #	Monsanto #
00-041-03n	2000-108XRAB
00-041-06n	2000-111XRAB
00-041-04n	2000-109XRAB
00-059-02n	2000-181XRAB

I apologize for any inconvenience this may cause, please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric, Pierre, SD
G. Gingery, Montana Dept. of Agric, Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005216

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

August 10, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications, it was discovered there was an omitted line number. The following are the affected notifications.

USDA #	Monsanto #
00-041-03n	2000-108XRAB
00-041-06n	2000-111XRAB
00-041-04n	2000-109XRAB
00-059-02n	2000-181XRAB

I apologize for any inconvenience this may cause, please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric, Pierre, SD
G. Gingery, Montana Dept. of Agric, Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005217

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T. Wessels, Washington Dept. of Agric., Jefferson City, MO

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

OR120018_BR_005218

2000 Wheat Field Trial Report
USDA # 00-041-04n Monsanto # 2000-109XRAB

Biotech Field Compliance Team
June 29, 2001
Monsanto Company

Location
Site 1

County
Walla Walla

State
WA

Site 1

(b) (4)

Site 1

(b) (4)

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-041-04n Monsanto # 2000-109XRAB

Biotech Field Compliance Team
June 29, 2001
Monsanto Company

Location
Site 1

County
Walla Walla

State
WA

Site 1

Planting Date: April 6, 2000

Harvest/Destruct Date: August 4, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT13, lines TA S317, TA S621, TA S635

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth Characteristics: [CBI deleted]

Field Monitoring for Weediness Characteristics: [CBI deleted]

Field Monitoring for Plant Stand: [CBI deleted]

Site 1

Planting Date: April 10, 2000

Harvest/Destruct Date: August 8, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT13, lines TA S317, TA S621, TA S635

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth Characteristics: [CBI deleted]

Field Monitoring for Weediness Characteristics: [CBI deleted]

Field Monitoring for Plant Stand: [CBI deleted]

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-041-04n **Monsanto #2000-109XRAB**

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2066639202

County
Walla Walla

State
WA

Walla Walla County/WA (2066639202)

(b) (4)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-041-04n Monsanto #2000-109XRAB

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2066639202	Walla Walla	WA

Walla Walla County/WA (2066639202)

Planting Date: 04/06/2000

Harvest Date: 08/04/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/10/2000

Harvest Date: 08/08/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/10/00 12:17 pm

Notification Tracking Sheet

=====
Bp number: 00-041-06n
=====

App number: 2000-111XRAB
Received: 2/10/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/11/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/09/00
End movement: 2/08/01
Begin release: 2/09/00
End release: 2/08/01
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ayd</i>]	[2/10/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>if</i>]*	[2/11/2000]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KLW</i>]	[2/14/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Dest*	SD	*	*SCR *
Interstate	*Orig*	MO	*	*SCR *
Interstate	*Orig*	SD	*	*SCR *
Release	*	*SD	*	2*SCR *

5. <input type="checkbox"/> Enter genes into database	[]	[]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KLW</i>]	[2/28/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KLW</i>]	[2/28/00]

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-111XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 09, 2000

00-041-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-111XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A.,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

SD

(b) (4)

Spink County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (4)

Roberts County, SD, (b) (4) JSA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-111XRAB

(b) (4) Codington County, SD, (b) (4) JSA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4) USA,

Ship To:

MO

(b) (4) St. Louis County, MO, (b) (4) U.S.A

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO, (b) (6), (b) (7)(C), (b) (4) U.S.A,

SD

(b) (4) Spink County, SD, (b) (4) JSA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4) USA,

(b) (4) Roberts County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4) JSA, (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-111XRAB

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4) USA,
(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID
2000-111XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

(b) (4)

Roberts County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Spink County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

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CBI-DELETED

Monsanto Reference ID

2000-111XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

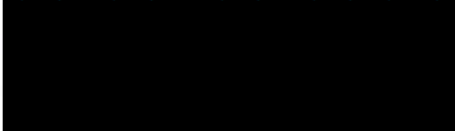
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2000

OR120018_BR_005242

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
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PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-111XRAB

Permit Unit

February 09, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-041-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-111XRAB

3. Applicant/Responsible Party

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700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-111XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12

(b) (4) (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15

(b) (4) (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-111XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b) (4)

CBI

(b) (4)

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Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' - (b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-111XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

MO, SD

DESTINATION:

MO, SD

Ship From:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A, (b) (4), (b) (6), (b) (7)(C)

MO,

SD

(b) (4)

Spink County, SD (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD, (b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4)

Roberts County, SD (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

SD, (b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-111XRAB

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD,

(b) (4), (b) (6), (b) (7)(C)

USA,

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MO,

SD

(b) (4)

Spink County, SD, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4)

Roberts County, SD, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
2000-111XRAB

(b) (4)

Codington County, SD (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

SD, (b) (4), (b) (6), (b) (7)(C) USA,

CONFIDENTIAL

Monsanto Reference ID

2000-111XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

(b) (4)

Roberts County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

SD,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Spink County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

SD,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-111XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 09, 2000

OR120018_BR_005255

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be

able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

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ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-111XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 09, 2000

00-041-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-111XRAB

3. Applicant/Responsible Party

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636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2000 - February 08, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2000-111XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:
MO, SD

DESTINATION:
MO, SD

Ship From:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)
U.S.A,

(b) (6), (b) (7)(C), (b) (4) MO,

SD

(b) (4)

Spink County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)
U.S.A,

(b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4) USA,

(b) (4)

Roberts County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4) USA,

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

(b) (4)

Codington County, SD (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

USA,

Ship To:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

SD

(b) (4)

Spink County, SD, (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (4)

Roberts County, SD (b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

(b) (4)

Codington County, SD, (b) (4) USA

CONTACT

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

SD

(b) (6), (b) (7)(C),

USA,

CBI-DELETED

Monsanto Reference ID

2000-111XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

(b) (4)

Roberts County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Spink County, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

SD,

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-111XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 09, 2000

OR120018_BR_005272

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-041-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-06n	Applicant #:	2000-111XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005273

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 2000

Dear Mr. Fridley:

Enclosed is notification 00-041-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-06n	Applicant #:	2000-111XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005274



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-041-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-041-06n	Applicant #:	2000-111XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

2/17/00

State:

MO

Rptloc01/R4

FEB 18 2000



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An Equal Opportunity Employer

OR120018_BR_005275



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 2000

Dear Mr. Fridley:

Enclosed is notification 00-041-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number:	00-041-06n	Applicant #:	2000-111XRAB
Received:	February 10, 2000	Effective:	March 11, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/16/200

State: South Dakota

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 16 2000

OR120018_BR_005276

February 28, 2000

(b) (6), (b) (7)(C)

700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 11, 2000.

Interstate movement and Release
Notification no. 00-041-06n (2000-111XRAB)
Regulated article - Wheat
Destinations - Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-041-06n

OR120018_BR_005277

MONSANTO

Food · Health · Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

August 10, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications, it was discovered there was an omitted line number. The following are the affected notifications.

USDA #	Monsanto #
00-041-03n	2000-108XRAB
00-041-06n	2000-111XRAB
00-041-04n	2000-109XRAB
00-059-02n	2000-181XRAB

I apologize for any inconvenience this may cause, please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric, Pierre, SD
G. Gingery, Montana Dept. of Agric, Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005278

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-041-06n Monsanto # 2000-111XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Roberts	SD
Site 2	Spink	SD (NOT PLANTED)

Roberts County, SD – Site 1

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-041-06n Monsanto # 2000-111XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Roberts	SD
Site 2	Spink	SD (NOT PLANTED)

Roberts County, SD – Site 1

Planting Date: April 11, 2000 and April 24, 2000

Harvest Date: August 2, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512; PV-TXGT13, lines TA_S635, TA_S621, TA_S2520, TA_S1081, TA_S5450, TA_S317; PV-TXGT17, line TA_S9250; PV-TXGT23, line TA_S9215; PV-TXGT23, line S7890

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-041-06n Monsanto #2000-111XRAB

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303318	Roberts	SD	
2147303319	Spink	SD	Not Planted

Roberts County/SD (2147303318)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-041-06n Monsanto #2000-111XRAB

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303318	Roberts	SD	
2147303319	Spink	SD	Not Planted

Roberts County/SD (2147303318)

Planting Date: 04/11/2000

Harvest Date: 08/02/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/08/00 2:17 pm

Notification Tracking Sheet

=====
Bp number: 00-039-09n
=====

App number: 2000-88XRAB
Received: 2/08/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/09/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/07/00
End movement: 2/06/01
Begin release: 2/07/00
End release: 2/06/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [wjd] | [2/9/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZL]* | [2/9/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KZL] | [2/10/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	WA	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	WA	*	*WR *
Release	*	WA	*	1*WR *

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [wjd] | [2/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZL] | [3/9/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZL] | [3/10/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-125XRAB

Permit Unit

February 14, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-09a

1. USDA Reference Number

2. Applicant Reference Number 2000-125XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-125XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- I

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-125XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-125XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 300 pounds of wheat seed to and from each location

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

Ship To:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-125XRAB

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ID

(b) (4), (b) (6), (b) (7)(C)

U.S.A.,

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A.,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MO,

CONFIDENTIAL

Monsanto Reference ID

2000-125XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (2)

ID

(b) (4)

Latah County, ID, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Latah County, ID, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-125XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 14, 2000

OR120018_BR_005295

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-125XRAB

Permit Unit

February 14, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-125XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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636/737-7085

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(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-125XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-125XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-125XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 300 pounds of wheat seed to and from each location

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4) ID, (b) (6), (b) (7)(C), (b) (4) U.S.A.,

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4) MO, (b) (6), (b) (7)(C), (b) (4) U.S.A.,

Ship To:

ID

(b) (4)

Latah County, ID, (b) (4) U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-125XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) ID: (b) (6), (b) (7)(C), (b) (4) U.S.A.,
(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A.

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-125XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (2)

ID

(b) (4)

Latah County, ID, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
ID, USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Latah County, ID, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (6), (b) (7)(C), (b) (4) ID, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-125XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 14, 2000

OR120018_BR_005305

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-88XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 07, 2000

00-039-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-88XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 07, 2000 - February 06, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-88XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

(b) (4)

Sedgwick County, KS(b) (4) USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

KS(b) (6), (b) (7)(C), (b) (4)

DISA(b) (6), (b) (7)(C), (b) (4)

WA

(b) (4)

(b) (4) USA

Whittman County,

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA, (b) (6), (b) (7)(C), (b) (4)

USA, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Ship To:

KS

(b) (4)

Sedgwick County, KS(b) (4) USA

CBI-DELETED

Monsanto Reference ID

2000-88XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Whittman County,

WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

WA

(b) (6), (b) (7)(C), (b) (4)

USA,

(b) (6), (b) (7)(C), (b) (4)

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

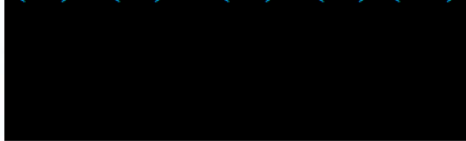
Monsanto Reference ID

2000-88XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 07, 2000

OR120018_BR_005311

CBI-DELETED

Monsanto Reference ID
2000-88XRAB

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

WA

(b) (4)

WA (b) (4) , USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 15, 2000

Dear Dr. Vega:

Enclosed is notification 00-046-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-09n	Applicant #:	2000-125XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005313

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2000

Dear Mr. Brown:

Enclosed is notification 00-046-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-09n	Applicant #:	2000-125XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005314



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 19 2000

PLANT INDUSTRIES

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 15, 2000

Dear Dr. Vega:

Enclosed is notification 00-046-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-09n	Applicant #:	2000-125XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature:

(b) (6), (b) (7)(C)

Date: Feb. 28, 2000

State: IDAHO

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2000

Dear Mr. Brown:

Enclosed is notification 00-046-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-09n	Applicant #:	2000-125XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael O. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/23/00

State: MO

Rptloc01/R4

FEB 23 2000



APHIS - Protecting American Agriculture

OR120018_BP_005316

P.03/10 314751005

DEPT OF AGRICULTURE

FEB-23-2000 14:28

March 6, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 16, 2000.

Interstate movement and Release
Notification no. 00-046-09n (2000-125XRAB)
Regulated article - Wheat
Destinations - Idaho, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-046-09n

OR120018_BR_005317

2000 Wheat Field Trial Report
USDA # 00-046-09n Monsanto # 2000-125XRAB

Biotech Field Compliance Team
July 11, 2001
Monsanto Company

Location
Site 1
Site 2

County
Latah
Latah

State
ID (NOT PLANTED)
ID

Site 2

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-046-09n Monsanto # 2000-125XRAB

Biotech Field Compliance Team
July 11, 2001
Monsanto Company

Location	County	State
Site 1	Latah	ID (NOT PLANTED)
Site 2	Latah	ID

Site 2

Planting Date: April 26, 2000

Harvest Date: August 31, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

General Results of Field Trial:
[CBI deleted]

2/15/00 2:24 pm

Notification Tracking Sheet

=====
Bp number: 00-046-10n
=====

App number: 2000-126XRAB
Received: 2/15/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/16/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/14/00
End movement: 2/13/01
Begin release: 2/14/00
End release: 2/13/01
Acre: 6.00
CBI status: CBI
Fax: 636-737-7085

- =====
- | | Initial | Date |
|--|----------|----------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [aip] | [2/15/2000] |
| 2. <input type="checkbox"/> Review by biotechnologist | [smk]* | [2/16/2000]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLo] | [2/17/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	AZ	*	*WR	*	[] []
Interstate	*Dest*	MO	*	*SCR	*	[] []
Interstate	*Dest*	MT	*	*WR	*	[] []
Interstate	*Orig*	AZ	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Interstate	*Orig*	MT	*	*WR	*	
Release	*	MT	*	2*WR	*	[] []

5. ☒ Enter genes into database [aip] [2/16/2000]
6. ☐ Letter of acknowledgement denial/withdraw [KLo] [3/13/00]*
7. ☐ Enter final data into database [KLo] [3/15/00]

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-126XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-10n

February 14, 2000

1. USDA Reference Number

2. Applicant Reference Number 2000-126XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite, BW251, and advanced breeding lines.

CONFIDENTIAL

Monsanto Reference ID

2000-126XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-126XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-126XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 500 pounds of wheat seed to and from each location.

ORIGIN:
AZ, MO, MT

DESTINATION:
AZ, MO, MT

Ship From:

AZ

(b) (4)

Yuma County, AZ,

(b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

Yuma, AZ

(b) (4), (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO,

(b) (4)

U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

MO,

(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

MT

(b) (4), (b) (6), (b) (7)(C)

Gallatin County, MT

(b) (4), (b) (6), (b) (7)(C)

USA

CONTACT

(b) (4), (b) (6), (b) (7)(C)

MT,

(b) (4), (b) (6), (b) (7)(C)

USA

CONFIDENTIAL

Monsanto Reference ID
2000-126XRAB

Ship To:

AZ

(b) (4)

Yuma County, AZ, 85366

CONTACT: Kim Shantz, Breeders of Westbred Varieties, 1611 E. 20th Street, Yuma, AZ, 85366

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A.

CONTACT: Hua-ping Zhou, Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO, 63198, U.S.A., 314/737-6431

MT

*Dale Clark, 8111 Timberline Dr, Bozeman, Gallatin County, MT, 59718-8184, USA

CONTACT: Dale Clark, Dale Clark, 8111 Timberline Dr, Bozeman, MT, 59718-8184, USA

CONFIDENTIAL

Monsanto Reference ID

2000-126XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (2)

MT

(b) (4), (b) (6), (b) (7)(C)

Gallatin County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER: D

(b) (4), (b) (6), (b) (7)(C)

MT

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Pondara County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

MT

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63108

PHONE (314) 694-1000

<http://www.monsanto.com>

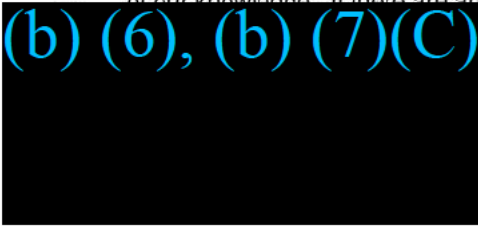
Monsanto Reference ID

2000-126XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 14, 2000

OR120018_BR_005327

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-126XRAB

February 14, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-126XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite, BW251, and advanced breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-126XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 500 pounds of wheat seed to and from each location.

ORIGIN:
AZ, MO, MT

DESTINATION:
AZ, MO, MT

Ship From:

AZ

(b) (4)

Yuma County, AZ, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

AZ, (b) (4), (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO, (b) (4) S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

MO, (b) (4), (b) (6), (b) (7)(C)

MT

(b) (4), (b) (6), (b) (7)(C)

Gallatin County, MT

(b) (4), (b) (6), (b) (7)(C)

USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C)

USA

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

Ship To:

AZ

(b) (4)

Yuma County, AZ (b) (4)

CONTACT

(b) (4), (b) (6), (b) (7)(C)

AZ

(b) (4), (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO, (b) (4) S.A.

CONTACT

(b) (4), (b) (6), (b) (7)(C)

U.S.A.,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MO,

MT

(b) (4), (b) (6), (b) (7)(C)

Gallatin County, MT

(b) (4), (b) (6), (b) (7)(C)

USA

CONTACT

(b) (4), (b) (6), (b) (7)(C)

MT,

(b) (4), (b) (6), (b) (7)(C)

USA

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (2)

MT

(b) (4), (b) (6), (b) (7)(C)

Gallatin County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

MT,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Bozondara County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

MT

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-126XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 14, 2000

OR120018_BR_005337

MONSANTO

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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-126XRAB

Permit Unit

February 14, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-126XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite, BW251, and advanced breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 500 pounds of wheat seed to and from each location.

ORIGIN:

AZ, MO, MT

DESTINATION:

AZ, MO, MT

Ship From:

AZ

(b) (4)

Yuma County, AZ (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

Yuma, AZ,

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO (b) (4).S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A.

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

MT

(b) (6), (b) (7)(C), (b) (4)

Ballatin County, MT,

(b) (6), (b) (7)(C), (b) (4)

USA

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

USA

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

Ship To:

AZ

(b) (4)

Yuma County, AZ, (b) (4)

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

AZ, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A., (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

Gallatin County, MT, (b) (6), (b) (7)(C)

USA

CONTACT

(b) (6), (b) (7)(C), (b) (4)

, MT, (b) (6), (b) (7)(C), (b) (4)

USA

CBI-DELETED

Monsanto Reference ID

2000-126XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (2)

MT

(b) (6), (b) (7)(C), (b) (4) Gallatin County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4) USA

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C) Pondara County, MT, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:
MT, (b) (6), (b) (7)(C), (b) (4) USA

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-126XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 14, 2000

OR120018_BR_005344

file copy

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

February 15, 2000

Dear Mr. Caravetta:

Enclosed is notification 00-046-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-10n	Applicant #:	2000-126XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005345

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2000

Dear Mr. Brown:

Enclosed is notification 00-046-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-10n	Applicant #:	2000-126XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005346

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 15, 2000

Dear Dr. Gingery:

Enclosed is notification 00-046-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-10n	Applicant #:	2000-126XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005347



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

FAXED

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

February 15, 2000

Dear Mr. Caravetta:

Enclosed is notification 00-046-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-10n	Applicant #:	2000-126XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

R. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: **(b) (6), (b) (7)(C)**

Date: 3-2-00

State: Arizona

Rptloc01/R4

MAR 2 2000



APHIS - Protecting American Agriculture

OR120018_BR_005348 An Equal Opportunity Employer

P.01/04 6025420999

AZ DEPT OF AGRICULTURE

MAR-02-2000 09:16



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2000

Dear Mr. Brown:

Enclosed is notification 00-046-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-10n	Applicant #:	2000-126XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/23/00

State: MO

Rptloc01/R4

FEB 23 2000



APHIS - Protecting American Agriculture

OR120018_BR_005349

An Equal Opportunity Employer

3147510025 P.02/10

DEPT OF AGRICULTURE

FEB-23-2000 14:27



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

gk

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 15, 2000

Dear Dr. Gingery:

Enclosed is notification 00-046-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-10n	Applicant #:	2000-126XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/22/00

State: Montana

Rptloc01/R4



March 13, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 16, 2000.

Interstate movement and Release
Notification no. 00-046-10n (2000-126XRAB)
Regulated article - Wheat
Destinations - Arizona, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

G. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-046-10n

OR120018_BR_005351

Confirmation Report-Memory Send

Time : Mar-14-00 05:01pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 960
Date : Mar-14 05:00pm
To : 916367377085
Document Pages : 01
Start time : Mar-14 05:00pm
End time : Mar-14 05:01pm
Pages sent : 01
Job number : 960

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 13, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63108

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 16, 2000.

Interstate movement and Release
Notification no. 00-046-10a (2000-126XRAB)
Regulated article - Wheat
Destinations - Arizona, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Dr. Elaine H. Hines, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
G. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stacks, PPQ, WR, Sacramento, CA



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An Equal Opportunity Employer

OR120018_BR_005352

CONFIDENTIAL

**2000 Wheat Field Test Report
USDA #00-046-10n Monsanto #2000-126XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147303425	Gallatin County	MT
2147316846	Pondera County	MT

Gallatin County/MT (2147303425)

(b) (4)

(b) (4)

Pondera County/MT (2147316846)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2000 Wheat Field Test Report
USDA #00-046-10n Monsanto #2000-126XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147303425	Gallatin County	MT
2147316846	Pondera County	MT

Gallatin County/MT (2147303425)

Planting Date: 05/23/2000

Harvest Date: 08/24/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Pondera County/MT (2147316846)

Planting Date: 05/16/2000

Harvest Date: 09/12/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/15/00 2:24 pm

Notification Tracking Sheet

=====
Bp number: 00-046-11n
=====

App number: 2000-127XRAB
Received: 2/15/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/16/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/14/00
End movement: 2/13/01
Begin release: 2/14/00
End release: 2/13/01
Acre: 6.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [2/15/2000] |
| 2. <input type="checkbox"/> Review by biotechnologist | [SMK]* | [2/16/2000] |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [K2L0] | [2/17/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*MN	*	*NER *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*MN	*	*NER *
Interstate	*Orig*MO	*	*SCR *
Release	* *MN	*	2*NER *

- | | | |
|--|----------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [2/16/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [K2L0] | [3/23/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [K2L0] | [3/24/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-127XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-11n

February 14, 2000

1. USDA Reference Number

2. Applicant Reference Number 2000-127XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite, BW251, and advanced breeding lines.

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Monsanto Reference ID

2000-127XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-127XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [(b) (4)]

(b) (4)

CBI

Gene: CTP7-CP4 -- [(b) (4)]

(b) (4)

CBI

(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [(b) (4)]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [(b) (4)]

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-127XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 300 pound of wheat seed to and from each location.

ORIGIN:
MN, MO

DESTINATION:
MN, MO

Ship From:

MN

(b) (4) Ramsey County, MN, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A.

MO

(b) (4) St. Louis County, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A.

Ship To:

MN

(b) (4) Ramsey County, MN, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-127XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) U.S.A.

MO

(b) (4) St. Louis County, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID

2000-127XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (2)

MN

(b) (4)

acres.

Polk County, MN, USA, 3

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

MN, (b) (4), (b) (6), (b) (7)(C) USA

(b) (4)

Ramsey County, MN, U.S.A., 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A.

(b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-127XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 14, 2000

OR120018_BR_005366

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-127XRAB

February 14, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-046-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-127XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite, BW251, and advanced breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 300 pound of wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From:

MN

(b) (4)

Ramsey County, MN, (b) (4) .S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

MN, (b) (6), (b) (7)(C), U.S.A.

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

U.S.A.,

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MO,

Ship To:

MN

(b) (4)

Ramsey County, MN (b) (4) U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4) MN. (b) (6), (b) (7)(C), (b) (4) J.S.A.

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A.

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (2)

MN

(b) (4)

, Polk County, MN, USA, 3

acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

MN, (b) (6), (b) (7)(C), (b) (4) USA

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Ramsey County, MN, U.S.A., 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4) MN, (b) (6), (b) (7)(C), (b) (4) U.S.A.

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

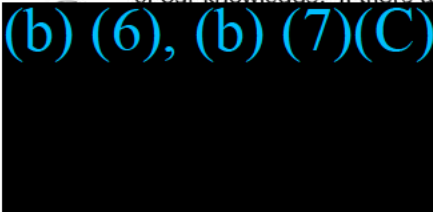
Monsanto Reference ID

2000-127XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 14, 2000

OR120018_BR_005376

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-127XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 14, 2000

00-046-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-127XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

priscilla.e.hunter@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2000 - February 13, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite, BW251, and advanced breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMOVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 300 pound of wheat seed to and from each location.

ORIGIN:
MN, MO

DESTINATION:
MN, MO

Ship From:

MN

(b) (4)

Ramsey County, MN, (b) (4) J.S.A.

CONTACT:

(b) (6), (b) (7)(C), (b) (4)

MN (b) (6), (b) (7)(C), (b) (4) J.S.A.

MO

(b) (4)

St. Louis County, MC (b) (4) J.S.A.

CONTACT:

REDACTED
(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MO, J.S.A. (b) (6), (b) (7)(C), (b) (4)

Ship To:

MN

(b) (4)

amsey County, MN, (b) (4) U.S.A.

CBI-DELETED

Monsanto Reference ID
2000-127XRAB

CONTACT (b) (6), (b) (7)(C), (b) (4) MN, (b) (6), (b) (7)(C), (b) (4) U.S.A.

MO

(b) (4) St. Louis County, MO (b) (4), U.S.A.

CONTACT: (b) (6), (b) (7)(C), (b) (4) MO,
(b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

CBI-DELETED

Monsanto Reference ID

2000-127XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (2)

MN

(b) (4)

Polk County, MN, USA, 3

acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MN, (b) (6), (b) (7)(C), (b) (4) USA

(b) (4)

Ramsey County, MN, U.S.A., 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MN, (b) (6), (b) (7)(C), (b) (4) U.S.A.

MONSANTO

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CBI-DELETED

Monsanto Reference ID

2000-127XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 14, 2000

OR120018_BR_005383

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 15, 2000

Dear Dr. Hanks:

Enclosed is notification 00-046-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-11n	Applicant #:	2000-127XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005384

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2000

Dear Mr. Brown:

Enclosed is notification 00-046-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-11n	Applicant #:	2000-127XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005385

00-046-11n



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

faxed 3-23-00

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 15, 2000

Dear Dr. Hanks:

Enclosed is notification 00-046-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-11n	Applicant #:	2000-127XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. HanksSignature: **(b) (6), (b) (7)(C)**Date: 3-23-00State: MN

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2000

Dear Mr. Brown:

Enclosed is notification 00-046-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-046-11n	Applicant #:	2000-127XRAB
Received:	February 15, 2000	Effective:	March 16, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

2/23/00

State:

MO

Rptloc01/R4

FEB 23 2000



APHIS - Protecting American Agriculture

OR120018_BR_005387

An Equal Opportunity Employer

P.01/10 3147510005

DEPT OF AGRICULTURE

FEB-23-2000 14:27

March 23, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2000.

Interstate movement and Release
Notification no. 00-046-11n (2000-127XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
S. Wood, PPQ, NER, Raleigh, NC
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-046-11n

OR120018_BR_005388

Confirmation Report-Memory Send

Time : Mar-23-00 06:04pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 361
Date : Mar-23 06:03pm
To : 916367377085
Document Pages : 01
Start time : Mar-23 06:03pm
End time : Mar-23 06:04pm
Pages sent : 01
Job number : 361

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

(b) (6), (b) (7)(C)

March 23, 2000

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2000.

Interstate movement and Release
Notification no. 00-046-11n (2000-127XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers. (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
S. Wood, PPQ, NER, Raleigh, NC
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_005389

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-046-11n Monsanto # 2000-127XRAB

Biotech Field Compliance Team
August 3, 2001
Monsanto Company

Location
Site #1
Site # 2

County
Polk
Ramsey

State
MN
MN

Site 1

(b) (4)

Site 2

(b) (4)

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-046-11n Monsanto # 2000-127XRAB

Biotech Field Compliance Team
August 3, 2001
Monsanto Company

Location	County	State
Site #1	Polk	MN
Site # 2	Ramsey	MN

Site 1

Planting Date: May 15, 2000

Harvest Date: August 15, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

Site 2

Planting Date: May 9, 2000

Harvest Date: August 11, 2000 (selected heads); August 15, 2000 (remaining heads)

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

CBI-DELETED

Monitoring for Volunteers[: [CBI deleted]

2/17/00 12:31 pm

Notification Tracking Sheet

=====
Bp number: 00-047-03n
=====

App number: 2000-131XR
Received: 2/16/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/17/00
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement:
End movement:
Begin release: 2/15/00
End release: 2/14/01
Acre: 5.00
CBI status: CBI

Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ajd</i>]	[2/17/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>/</i>]*	[2/24/00]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KLNO</i>]	[2/25/00]*
4. <input type="checkbox"/> State response		

	Release	O/d	Loc	Site	Reg		
		*	*KS	*	1*SCR	*	
5. <input checked="" type="checkbox"/> Enter genes into database							[<i>ajd</i>] [2/29/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw							[<i>KLNO</i>] [4/12/00]*
7. <input checked="" type="checkbox"/> Enter final data into database							[<i>KLNO</i>] [4/17/00]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-131XR

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 15, 2000

00-047-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-131XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Release

February 15, 2000 - February 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-131XR

designation of transformed line: 33319

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVa/12 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

CBI

(b) (4)

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-131XR

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b) (4) CBI
(b) (4)

Gene: CTP2-CP4 -- (b) (4) CBI
(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b) (4) CBI
(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b) (4) CBI
(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-131XR

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Release

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

(b) (4)

Harvey County, KS, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-131XR

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 15, 2000

OR120018_BR_005399

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-131XR

February 15, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-047-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-131XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Release

February 15, 2000 - February 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-131XR

designation of transformed line: 33319

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-131XR

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-131XR

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Release

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

(b) (4), (b) (6), (b) (7)(C)

Harvey County, KS, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-131XR

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 15, 2000

OR120018_BR_005407

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-131XR

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 15, 2000

00-047-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-131XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Release

February 15, 2000 - February 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-131XR

designation of transformed line: 33319

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-131XR

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-131XR

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Release

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

(b) (6), (b) (7)(C), (b) (4)

Harvey County, KS, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (7)(C), (b) (4)

KS

(b) (6), (b) (7)(C), (b) (4)

USA

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI-DELETED

Monsanto Reference ID

2000-131XR

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 15, 2000

OR120018_BR_005412

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 17, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-047-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-047-03n	Applicant #:	2000-131XR
Received:	February 16, 2000	Effective:	March 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	KS		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005413

April 12, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 12, 2000.

Release

Notification no. 00-047-03n (2000-131XR)

Regulated article - Wheat

Destination - Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official, and the Regional Program Manager, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-047-03n

OR120018_BR_005414

Confirmation Report-Memory Send

Time : Apr-13-00 02:26pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 915
Date : Apr-13 02:25pm
To : 916367377085
Document Pages : 01
Start time : Apr-13 02:25pm
End time : Apr-13 02:26pm
Pages sent : 01
Job number : 915

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 12, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 12, 2000.

Release

Notification no. 00-047-03n (2000-131XR)
Regulated article - Wheat
Destination - Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official, and the Regional Program Manager, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005415



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

December 6, 2002

Mr. Tony Roman
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

RE: USDA # 00-047-03n, Monsanto # 2000-131XR

Dear Mr. Roman:

A typographical error has been found in the notification referenced above. The transformed line for construct PV-TXGT10 should be listed as 33391, not 33319.

If you have any questions, please call me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-047-03n **Monsanto # 2000-131XR**

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Harvey

State
KS

Harvey County, KS

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-047-03n Monsanto # 2000-131XR

July 12, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Harvey

State
KS

Harvey County, KS

Planting Date: July 10, 2000

Destruct Date: August 18, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Growth Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Monitoring for Volunteers: [CBI deleted]

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-047-03n **Monsanto #2000-131XR**

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147303350	Harvey	KS

Harvey County/KS (2147303350)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

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* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

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CBI-DELETED

2000 Wheat Field Test Report
USDA #00-047-03n Monsanto #2000-131XR

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147303350	Harvey	KS

Harvey County/KS (2147303350)

Planting Date: 07/10/2000

Destruct Date: 08/18/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

=====

Bp number: 00-053-11n

=====

App number: 2000-142XRAB
 Received: 2/22/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/23/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[2/24/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[LMK]*	[2/28/2000]
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[K&N]	[2/29/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg	Initial	Date
Interstate *Dest*KS *				*SCR *	[]	[]
Interstate *Dest*ND *				*SCR *	[]	[]
Interstate *Orig*KS *				*SCR *		
Interstate *Orig*ND *				*SCR *		
Release * *ND *				1*SCR *	[]	[]
5. <input checked="" type="checkbox"/> Enter genes into database					[ajd]	[2/28/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw					[K&N]	[3/20/00]*
7. <input checked="" type="checkbox"/> Enter final data into database					[K&N]	[3/22/00]

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-142XRAB

Permit Unit

February 16, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-053-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-142XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 16, 2000 - March 17, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-142XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-142XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- (b) (4)

CBI

Gene: CTP7-CP4 -- (b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b) (4)

CBI

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Monsanto Reference ID

2000-142XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 800 pounds of wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

(b) (4)

Sedgwick County/Province, KS (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND, USA,

] - CBI

ND

*[

(b) (4)

Adams County/Province, ND, USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND, USA,

] - CBI

Ship To:

KS

(b) (4)

Sedgwick County/Province, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2000-142XRAB

CONTACT (b) (4), (b) (6), (b) (7)(C) ND, USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

(b) (4) Adams County/Province, ND, USA

CONTACT (b) (4), (b) (6), (b) (7)(C) ND, USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-142XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4)

Adams County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) ND, USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

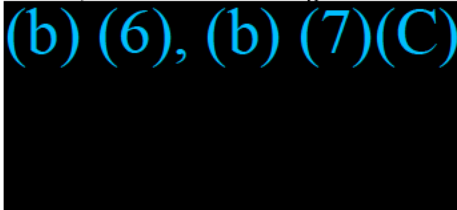
Monsanto Reference ID

2000-142XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 16, 2000

OR120018_BR_005433

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-142XRAB

Permit Unit

February 16, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-053-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-142XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 16, 2000 - March 17, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/l5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 800 pounds of wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Adams County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

ND

[CBI Deleted] -- *Adams County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Adams County/Province, ND, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-142XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

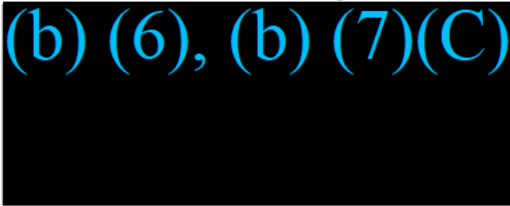
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 16, 2000

OR120018_BR_005443

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-142XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 16, 2000

00-053-11n

1. USDA Reference Number

2. Applicant Reference Number 2000-142XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 16, 2000 - March 17, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal
[REDACTED] gene (CP4) from an *Agrobacterium* species, strain
CP4.

Not A FOIA Deletion

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal
[REDACTED] gene (CP4) from an *Agrobacterium* species, strain
CP4.

Not A FOIA Deletion

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-amino acid histidine-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Not A FOIA Deletion

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 800 pounds of wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Adams County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

ND

[CBI Deleted] -- *Adams County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-142XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Adams County/Province, ND, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED


Monsanto Reference ID
2000-142XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
February 16, 2000

OR120018_BR_005450

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-053-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-11n	Applicant #:	2000-142XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005451

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-053-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-11n	Applicant #:	2000-142XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005452



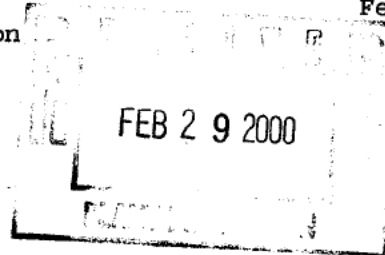
United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000



Dear Mr. Sim IV:

Enclosed is notification 00-053-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-11n	Applicant #:	2000-142XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~ state acknowledges receipt of this notification but
~~State DOES NOT CONCUR and offers the following reasons:~~ cannot evaluate.

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 3/8/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_005453

MAR 15 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-053-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-11n	Applicant #:	2000-142XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature: (b) (6), (b) (7)(C)

Date: 3-9-2000

State: ND

Rptloc01/R4

MAR 10 2000



APHIS - Protecting American Agriculture

OR120018_BR_005454

P. 5 NO. 460

ND AG DEPT

MAR. 9. 2000 4:19PM

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2000.

Interstate movement and Release
Notification no. 00-053-11n (2000-142XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-053-11n

OR120018_BR_005455

Confirmation Report-Memory Send

Time : Mar-21-00 03:52pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 218
Date : Mar-21 03:47pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 03:47pm
End time : Mar-21 03:50pm
Pages sent : 01
Job number : 218

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2000.

Interstate movement and Release
Notification no. 00-053-11n (2000-142XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, FWO, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005456

2000 Wheat Field Trial Report

USDA # ~~00-053-11n~~

Monsanto # 2000-142XRAB

Priscilla E. Hunter

June 11, 2001

Monsanto Company

Location

Hettinger Research Center

County

Adams

State

ND

Adams County, ND

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-053-11n Monsanto # 2000-142XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Adams

State
ND

Adams County, ND

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-053-11n Monsanto # 2000-142XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Adams	ND

Adams County, ND

Planting Date: May 10, 2000

Destruct Date: July 13 and July 21, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Additional Comments:
[CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/24/00 12:58 pm

Notification Tracking Sheet

Bp number: 00-053-12n

App number: 2000-146XRAB

Received: 2/22/00

Institution: Monsanto

Recipient: Wheat

Status: Pending

Effective date: 3/23/00

Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Begin movement: 2/17/00

End movement: 2/16/01

Begin release: 2/17/00

End release: 3/16/01

Acre: 10.00

CBI status: CBI

(b) (6), (b) (7)(C)

Fax: 636-737-7085

Initial

Date

1. ☒ Assign Bp number and initial data entry[*ajd*]

[2/24/2000]

2. ☒ Review by biotechnologist[*fmk*] *

[2/28/2000] *

3. ☒ Letter of notification to State Fed-ex[*KLW*]

[2/29/00] *

4. ☐ State response

O/d Loc Site Reg

Interstate *Dest*MN * *NER *

[] []

Interstate *Dest*MO * *SCR *

[] []

Interstate *Dest*OR * *WR *

[] []

Interstate *Orig*MN * *NER *

Interstate *Orig*MO * *SCR *

Interstate *Orig*OR * *WR *

Release * *MN * 1*NER *

[] []

Release * *OR * 1*WR *

[] []

5. ☒ Enter genes into database[*ajd*]

[2/28/2000]

6. ☒ Letter of acknowledgement/denial/withdraw[*KLW*]

[3/23/00] *

7. ☒ Enter final data into database[*KLW*]

[3/24/00]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-146XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 17, 2000

00-053-12n

1. USDA Reference Number

2. Applicant Reference Number 2000-146XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2000 - March 18, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-146XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/5

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-146XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-146XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 35,000 pounds of wheat seed, and plants to/ from each location

ORIGIN:

MN, MO, OR

DESTINATION:

MN, MO, OR

Ship From:

MN

*[(b) (4) Wilkin County/Province,
MN, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, 56522, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) St. Louis County/Province, MO, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-146XRAB

OR

*[(b) (4) Benton County/Province, OR (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) OR, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

MN

*[(b) (4) Wilkin County/Province,
MN, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) St. Louis County/Province, MO, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-146XRAB

OR

* [REDACTED] (b) (4) Benton County/Province, OR (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) OR, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-146XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1), OR (1)

MN

(b) (4) Wilkin County/Province,
MN, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C)

] - CBI

OR

(b) (4) Jefferson County/Province, OR,
USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OR (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-146XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 17, 2000

OR120018_BR_005470

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-146XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 17, 2000

00-053-12n

1. USDA Reference Number

2. Applicant Reference Number 2000-146XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2000 - March 18, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 35,000 pounds of wheat seed, and plants to/ from each location

ORIGIN:

MN, MO, OR

DESTINATION:

MN, MO, OR

Ship From:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO

[CBI Deleted] -- *St. Louis County/Province, MO

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

OR

[CBI Deleted] -- *Benton County/Province, OR

Ship To:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO

[CBI Deleted] -- *St. Louis County/Province, MO

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

OR

[CBI Deleted] -- *Benton County/Province, OR

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1), OR (1)

MN

[CBI Deleted] -- Wilkin County/Province, MN, 5 acres

OR

[CBI Deleted] -- Jefferson County/Province, OR, USA, 5 acres

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-146XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 17, 2000

OR120018_BR_005481

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-146XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 17, 2000

00-053-12n

1. USDA Reference Number

2. Applicant Reference Number 2000-146XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 17, 2000 - March 18, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]



Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 35,000 pounds of wheat seed, and plants to/ from each location

ORIGIN:

MN, MO, OR

DESTINATION:

MN, MO, OR

Ship From:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO

[CBI Deleted] -- *St. Louis County/Province, MO

CBI-DELETED

Monsanto Reference ID
2000-146XRAB

OR

[CBI Deleted] -- *Benton County/Province, OR

Ship To:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO

[CBI Deleted] -- *St. Louis County/Province, MO

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

OR

[CBI Deleted] -- *Benton County/Province, OR

CBI-DELETED

Monsanto Reference ID

2000-146XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1), OR (1)

MN

[CBI Deleted] -- Wilkin County/Province, MN, 5 acres

OR

[CBI Deleted] -- Jefferson County/Province, OR, USA, 5 acres

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

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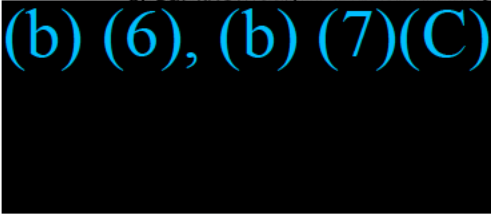
Monsanto Reference ID

2000-146XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 17, 2000

OR120018_BR_005489

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 24, 2000

Dear Dr. Hanks:

Enclosed is notification 00-053-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-12n	Applicant #:	2000-146XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO OR		
Release destination:	MN OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005490

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-053-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-12n	Applicant #:	2000-146XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO OR		
Release destination:	MN OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005491

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 24, 2000

Dear Mr. Griesbach:

Enclosed is notification 00-053-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-12n	Applicant #:	2000-146XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO OR		
Release destination:	MN OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005492



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

faxed 3-23-00

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 24, 2000

Dear Dr. Hanks:

Enclosed is notification 00-053-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-12n	Applicant #:	2000-146XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO OR		
Release destination:	MN OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *3-23-00*

State: *MN*

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-053-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-12n	Applicant #:	2000-146XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO OR		
Release destination:	MN OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Harkner, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3-14-00

State: MO

Rptloc01/R4

MAR 14 2000



APHIS - Protecting American Agriculture

OR120018_BR_005494

P.01/09 3147510005

DEPT OF AGRICULTURE

MAR-14-2000 15:21



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Post/IR Date # of pages
Fax Note 3/21/00
To Dianne Hatmaker
Fax# 301-734-8910
From Dan Hilburn
Phone# 503-986-4663

February 24, 2000

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

Dear Mr. Griesbach:

Enclosed is notification 00-053-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-053-12n	Applicant #:	2000-146XRAB
Received:	February 22, 2000	Effective:	March 23, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO OR		
Release destination:	MN OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION



State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Daniel J. Hilburn

Signature:

(b) (6), (b) (7)(C)

Date: March 21, 2000

State: Oregon

Rptloc01/R4



The movement of plants must comply with Oregon's Japanese beetle (JB) quarantine.



March 23, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2000.

Interstate movement and Release
Notification no. 00-053-12n (2000-146XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri, Oregon

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Oregon concurs with APHIS determination, however, the movement of plants must comply with Oregon's Japanese beetle Quarantine.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
J. Griesbach, Oregon Dept. of Agric., Salem, OR
S. Wood, PPQ, NER, Raleigh, NC

OR120018_BR_005496

D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-053-12n

Confirmation Report-Memory Send

Time : Mar-24-00 10:09am
Tel line 1 :
Tel line 2 :
Name :

Job number : 371
Date : Mar-24 10:07am
To : 916367377085
Document Pages : 02
Start time : Mar-24 10:07am
End time : Mar-24 10:08am
Pages sent : 02
Job number : 371

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 23, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2000.

Interstate movement and Release
Notification no. 00-053-12n (2000-146KRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri, Oregon

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Oregon concurs with APHIS determination, however, the movement of plants must comply with Oregon's Japanese beetle Quarantine.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
J. Griesbach, Oregon Dept. of Agric., Salem, OR



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005498

2000 Wheat Field Trial Report
USDA # 00-053-12n Monsanto # 2000-146XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location

Site 1

Site 2

County

Wilkin

Jefferson

State

MN

OR

Wilkin County, MN – Site 1

(b) (4)

Jefferson County, OR – Site 2

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-053-12n Monsanto # 2000-146XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Wilkin	MN
Site 2	Jefferson	OR

Wilkin County, MN – Site 1

Planting Date: April 27, 2000

Harvest Date: August 1, August 8, August 11, August 15, August 22, August 29 and September 5, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391.

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Additional Comments: [CBI deleted]

Jefferson County, OR – Site 2

Planting Date: April 26, 2000

Harvest Date: August 25-September 29, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

2/24/00 12:58 pm

Notification Tracking Sheet

=====

Bp number: 00-054-03n

=====

App number: 2000-167XRAB Begin movement: 2/22/00
 Received: 2/23/00 End movement: 2/21/01
 Institution: Monsanto Begin release: 2/22/00
 Recipient: Wheat End release: 2/21/01
 Status: Pending Acre: 10.00
 Effective date: 3/24/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

- | | Initial | Date |
|--|-----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ayd</i>] | [2/24/2000] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>fmk</i>]* | [2/29/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [<i>KLN</i>] | [2/29/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	ND	*	*SCR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	ND	*	*SCR *
Release	*	*ND	*	2*SCR *

- | | Initial | Date |
|---|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ayd</i>] | [2/28/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw | [<i>KLN</i>] | [3/20/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLN</i>] | [3/22/00] |

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Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-167XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-167XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-167XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-167XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-167XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of Wheat seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

* (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

ND

* (b) (4) Burke County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

* (b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-167XRAB

* (b) (4) Mountrail County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

Ship To:

KS

* (b) (4) edgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

ND

*[(b) (4) Burke County/Province, ND (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-167XRAB

*[(b) (4) Mountrail County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-167XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[(b) (4), (b) (6), (b) (7)(C)], Mountrail County/Province, ND, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Mountrail County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-167XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005512

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO

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00-054-03n

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-167XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-167XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of Wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Mountrail County/Province, ND

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

[CBI Deleted] -- *Mountrail County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Mountrail County/Province, ND

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

[CBI Deleted] -- *Mountrail County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Mountrail County/Province, ND, 5 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 5 acres

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-167XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005523

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CBP-UL-ETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-167XRAB

February 22, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-167XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal
phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~
CP4.

Not a FOIA Deletion

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal
phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~
CP4.

Not a FOIA Deletion

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal
phosphate synthase gene (CP4) from an *Agrobacterium* species, strain
CP4.

Terminator: M1 -- [CBI Deleted]

Not a FOIA Deletion

CBI

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of Wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Mountrail County/Province, ND

CBI-DELETED

Monsanto Reference ID
2000-167XRAB

[CBI Deleted] -- *Mountrail County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Mountrail County/Province, ND

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

[CBI Deleted] -- *Mountrail County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-167XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Mountrail County/Province, ND, 5 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 5 acres

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

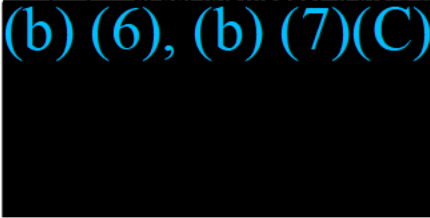
Monsanto Reference ID

2000-167XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005531

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-054-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-03n	Applicant #:	2000-167XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005532

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-054-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-03n	Applicant #:	2000-167XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005533



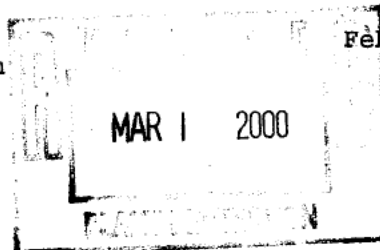
United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000



Dear Mr. Sim IV:

Enclosed is notification 00-054-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-03n	Applicant #:	2000-167XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*State acknowledges receipt of
this notification but cannot
evaluate.*

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 3/8/00

State: Kansas

Rptloc01/R4



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OR120018_BR_005534

MAR 15 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-054-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-03n	Applicant #:	2000-167XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 2-9-2000

State: ND

Rptloc01/R4

MAR 10 2000



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OR120018_BR_005535

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NO. 460 P. 7

ND AG DEPT

MAR. 9. 2000 4:19PM

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-03n (2000-167XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-054-03n

OR120018_BR_005536

Confirmation Report-Memory Send

Time : Mar-21-00 03:48pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 206
Date : Mar-21 03:31pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 03:47pm
End time : Mar-21 03:47pm
Pages sent : 01
Job number : 206

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

(b) (6), (b) (7)(C)

March 20, 2000

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-03n (2000-167KRAA)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



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OR120018_BR_005537

2000 Wheat Field Trial Report
USDA # ~~00-054-03n~~ Monsanto # 2000-167XRAB

(b) (6), (b) (7)(C)

June 12, 2001
Monsanto Company

Location

Monte Schenfisch Farm
West Dakota Feed and Seed

County

Mountrail
Mountrail

State

ND
ND

Mountrail County, ND

(b)(4)

Mountrail County, ND

(b)(4)

(b)(4)

Mountrail County, ND

(b)(4)

(b)(4)

2000 Wheat Field Trial Report
USDA # 00-054-03n Monsanto # 2000-167XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Mountrail	ND
Site 2	Mountrail	ND

Mountrail County, ND – Site 1

(b)(4)

Mountrail County, ND- Site 2

(b)(4)

(b)(4)

Mountrail County, ND

(b)(4)

(b)(4)

2000 Wheat Field Trial Report
USDA # 00-054-03n Monsanto # 2000-167XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Mountrail	ND
Site 2	Mountrail	ND

Mountrail County, ND- Site 1

Planting Date: May 17, 2000

Destruct Date: August 1, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Monitoring for Volunteer Plants:[CBI deleted]

Mountrail County, ND – Site 2

Planting Date: May 16, 2000

Harvest Date: September 15, 2000

Destruct Date: August 1, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Growth Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

Mountrail County, ND- Site 2

Planting Date: May 16, 2000

Destruct Date: August 1, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations or Plant Growth, Weediness and Plant Growth Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/24/00 12:58 pm

Notification Tracking Sheet

=====
Bp number: 00-054-04n
=====

App number: 2000-168XRAB Begin movement: 2/22/00
Received: 2/23/00 End movement: 2/21/01
Institution: Monsanto Begin release: 2/22/00
Recipient: Wheat End release: 2/21/01
Status: Pending Acre: 5.00
Effective date: 3/24/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: 636-737-6032 Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>aid</i>]	[2/24/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>KLH</i>]*	[2/28/00]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[<i>KLH</i>]	[2/29/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[]
Interstate	*Dest*	ND	*	*SCR	*	[]
Interstate	*Orig*	KS	*	*SCR	*	[]
Interstate	*Orig*	ND	*	*SCR	*	[]
Release	*	*ND	*	1*SCR	*	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[<i>aid</i>]	[2/28/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KLH</i>]	[3/20/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KLH</i>]	[3/22/00]

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-168XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-168XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

E-Mail

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Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-168XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-168XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b)(4)

(b)(4)

CBI

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Monsanto Reference ID

2000-168XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to nd from each location

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

*[(b)(4)] Sedgwick County/Province, KS, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
USA

ND,

] - CBI

ND

*[(b)(4)] Williams County/Province, ND, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
USA

ND,

] - CBI

Ship To:

KS

[(b)(4)] Sedgwick County/Province, KS, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-168XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND,
(b) (4), (b) (6), (b) (7)(C) USA

] - CBI

ND

*[(b) (4) Williams County/Province, ND (b) (4)
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND,
(b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-168XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[(b)(4)] Williams County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

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PHONE (314) 694-1000

<http://www.monsanto.com>

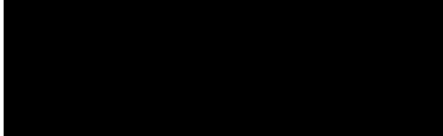
Monsanto Reference ID

2000-168XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005555

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-168XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 22, 2000

00-054-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-168XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

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EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to nd from each location

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID
2000-168XRAB

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Williams County/Province, ND, USA, 5 acres

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CBI-DELETED

MONSANTO COMPANY

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-168XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005565

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-168XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-168XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* CPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* CPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* ERSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to nd from each location

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID
2000-168XRAB

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-168XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Williams County/Province, ND, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>


Monsanto Reference ID

2000-168XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005572

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-054-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-04n	Applicant #:	2000-168XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005573

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-054-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-04n	Applicant #:	2000-168XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005574

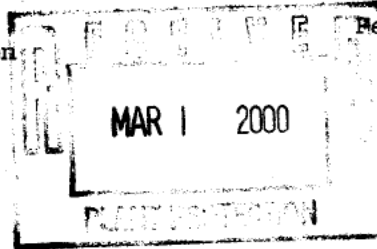


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281



February 24, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-054-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-04n	Applicant #:	2000-168XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*state acknowledges receipt of
this notification but
cannot evaluate.*

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 3/8/00

State: Kansas

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_005575

MAR 15 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-054-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 00-054-04n
Received: February 23, 2000
Institution: Monsanto
Interstate destination: KS ND
Release destination: ND

Applicant #: 2000-168XRAB
Effective: March 24, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-9-2000

State: ND

Rptloc01/R4

MAR 10 2000



APHIS - Protecting American Agriculture

OR120018_BR 200570

P. 460 NO.

ND AG DEPT

MAR. 9. 2000 4:19PM

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-04n (2000-168XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-054-04n

OR120018_BR_005577

Confirmation Report-Memory Send

Time : Mar-21-00 03:47pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 208
Date : Mar-21 03:32pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 03:47pm
End time : Mar-21 03:47pm
Pages sent : 01
Job number : 208

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-04n (2000-168XKAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sam, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_005578

2000 Wheat Field Trial Report
USDA # ~~00-054-04n~~ Monsanto # 2000-168XRAB

(b) (6), (b) (7)(C)
June 11, 2001
Monsanto Company

Location
Williston Research Center

County
Williams

State
ND

Williams County, ND

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-054-04n Monsanto # 2000-168XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Williams

State
ND

Williams County, ND

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-054-04n Monsanto # 2000-168XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Williams	ND

Williams County, ND

Planting Date: May 15, 2000

Harvest Date: August 21, 2000 (Weed control study)

Destruct Date: July 24, 2000 Tilled

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/24/00 12:58 pm

Notification Tracking Sheet

=====

Bp number: 00-054-05n

=====

App number: 2000-169XRAB Begin movement: 2/22/00
 Received: 2/23/00 End movement: 2/21/01
 Institution: Monsanto Begin release: 2/22/00
 Recipient: Wheat End release: 2/21/01
 Status: Pending Acre: 5.00
 Effective date: 3/24/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: 636-737-6032 Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ayd</i>]	[2/24/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>KLW</i>]*	[2/28/00]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[<i>KLW</i>]	[2/29/00]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*CO	*	*WR	*	[] []
Interstate	*Dest*MO	*	*SCR	*	[] []
Interstate	*Orig*CO	*	*WR	*	
Interstate	*Orig*MO	*	*SCR	*	
Release	*CO	*	1*WR	*	[] []

5. <input checked="" type="checkbox"/> Enter genes into database	[<i>ayd</i>]	[2/28/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KLW</i>]	[3/20/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KLW</i>]	[3/22/00]

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-169XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-169XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
CO, MO

DESTINATION:
CO, MO

Ship From:

CO

*[(b) (4)] Yuma County/Province, CO

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] CO

] - CBI

*[(b) (4)] Arapaho County/Province, CO, [(b) (4)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] CO, [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, [(b) (4)] U.S.A

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MO, [(b) (4), (b) (6), (b) (7)(C)] U.S.A,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

Ship To:

CO

*[(b) (4)] Yuma County/Province, CO

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO

] - CBI

*[(b) (4)] Arapaho County/Province, CO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-169XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1)

CO

[(b) (4) Yuma County/Province, CO, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) CO

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

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PHONE (314) 694-1000

<http://www.monsanto.com>

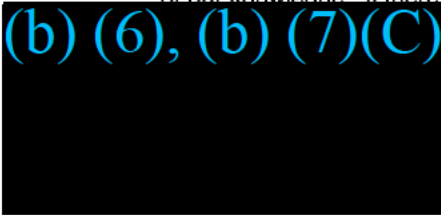
Monsanto Reference ID

2000-169XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005596

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-169XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 22, 2000

00-054-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-169XRAB

3. Applicant/Responsible Party

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700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
CO, MO

DESTINATION:
CO, MO

Ship From:

CO

[CBI Deleted] -- *Yuma County/Province, CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

Ship To:

CO

[CBI Deleted] -- *Yuma County/Province, CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1)

CO

[CBI Deleted] -- Yuma County/Province, CO, 5 acres

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-169XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005611

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Monsanto Reference ID

2000-169XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 22, 2000

00-054-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-169XRAB

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St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMOVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [~~CBI~~ Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana ~~CTP2~~ gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

CO, MO

DESTINATION:

CO, MO

Ship From:

CO

[CBI Deleted] -- *Yuma County/Province, CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

Ship To:

CO

[CBI Deleted] -- *Yuma County/Province, CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-169XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[CBI Deleted] -- Yuma County/Province, CO, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE • (314) 694-1000

<http://www.monsanto.com>

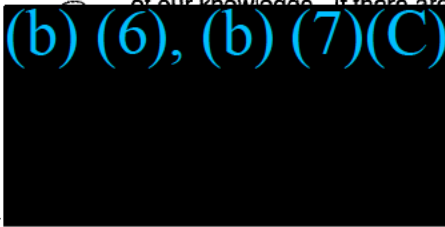
Monsanto Reference ID

2000-169XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005623

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 24, 2000

Dear Mr. Yergert:

Enclosed is notification 00-054-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-05n	Applicant #:	2000-169XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005624

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-054-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-05n	Applicant #:	2000-169XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005625



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

1700 River Road
Riverdale, MD 20737

RECEIVED
FEB 28 PM 1:18

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 24, 2000

Dear Mr. Yergert:

Enclosed is notification 00-054-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-054-05n
Received: February 23, 2000
Institution: Monsanto
Interstate destination: CO MO
Release destination: CO

Applicant #: 2000-169XRAB
Effective: March 24, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: (b) (6), (b) (7)(C)

Date: March 2, 2000

State: Colorado

Rptloc01/R4



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An Equal Opportunity Employer

MAR 2 2000

OR120018_BR_005626



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-054-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-05n	Applicant #:	2000-169XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Dr. Bonnie Hutchins, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3-14-00

State: MO

Rpt1oc01/R4

MAR 14 2000



March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-05n (2000-169XRAB)
Regulated article - Wheat
Destination - Colorado, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-054-05n

OR120018_BR_005628

Confirmation Report-Memory Send

Time : Mar-21-00 03:51pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 216
Date : Mar-21 03:45pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 03:47pm
End time : Mar-21 03:50pm
Pages sent : 01
Job number : 216

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-05n (2000-169XRAB)
Regulated article - Wheat
Destination - Colorado, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

(b) (6), (b) (7)(C)

R. Dianne Ratmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_005629

2000 Wheat Field Trial Report
USDA # ~~00-054-05n~~ Monsanto # 2000-169XRAB

(b) (6), (b) (7)(C)

June 12, 2001
Monsanto Company

Location
Irrigation Research Foundation

County
Yuma

State
CO

Yuma County, CO

(b) (4)

MONSANTO



August 2, 2001

Ms. Dianne Hatmaker
Animal and Plant Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Dear Ms. Hatmaker;

Field releases under the following USDA notifications have been completed and we are now submitting final reports as required. Please find reports for:

USDA#	Monsanto #	Crop
00-054-05n	2000-169XRAB	Wheat
00-040-05n	2000-92XRAB	Wheat
00-039-09n	2000-88XRAB	Wheat
00-040-06n	2000-93XRAB	Wheat
00-038-20n	2000-79XRAB	Wheat
00-059-07n	2000-188XRAB	Wheat
00-005-01n	2000-1XRAB	Wheat
00-053-11n	2000-142XRAB	Wheat
00-059-03n	2000-182XRAB	Wheat
00-054-04n	2000-168XRAB	Wheat
00-034-09n	2000-64XRAB	Wheat
00-039-07n	2000-085XRAB	Wheat
00-054-03n	2000-167XRAB	Wheat
99-266-02n	99-726XRAB	Wheat
00-063-15n	2000-208XRAB	Cotton
00-077-05n	2000-285XRAB	Cotton
00-077-04n	2000-284XRAB	Cotton
00-059-05n	2000-186XRAB	Cotton
00-042-02n	2000-41XR	Cotton
00-038-15n	2000-70XRAB	Cotton
00-038-23n	2000-82XRAB	Cotton

If you have any additional questions, please call me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

CONFIDENTIAL

2000 Wheat Field Trial Report

USDA # 00-054-05n

Monsanto # 2000-169XRAB

December 7, 2001

**Biotech Field Compliance Team
Monsanto Company**

**Location
Site 1**

**County
Yuma**

**State
CO**

Yuma County CO

(b)(4)

2000 Wheat Field Trial Report
USDA # 00-054-05n Monsanto # 2000-169XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Yuma	CO

Yuma County, CO

Planting Date: April 5, 2000

Harvest Date: July 19, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteers: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2/24/00 12:58 pm

Notification Tracking Sheet

=====

Bp number: 00-054-06n

=====

App number: 2000-170XRAB
 Received: 2/23/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/24/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: 636-737-6032
 Begin movement: 2/22/00
 End movement: 2/21/01
 Begin release: 2/22/00
 End release: 2/21/01
 Acre: 15.00
 CBI status: CBI
 Fax: 636-737-7085

- | | Initial | Date |
|--|-----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ayd] | [2/24/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZL] * | [2/28/00] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KZL] | [2/29/00] * |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*ND	*	*SCR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*ND	*	*SCR *
Release	* *ND	*	3*SCR *

[]	[]
[]	[]
[]	[]
[]	[]
[]	[]

- | | | |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ayd] | [2/28/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZL] | [3/20/00] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZL] | [3/22/00] |

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-170XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-170XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-170XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVa/12 (b)(4) (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 (b)(4) (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-170XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-170XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

* (b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

ND

* (b)(4) Cass County/Province, ND, (b)(4) U.S.A.

CONTACT:

(b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

* (b)(4) Cass County/Province, ND, USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-170XRAB

* (b)(4) Cass County/Province, ND, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

* (b)(4) Foster County/Province, ND, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

Ship To:

KS

(b)(4)

Sedgwick County/Province, KS (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

ND

* (b)(4) Cass County/Province, ND (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-170XRAB

* [(b)(4) Cass County/Province, ND, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

* [(b)(4) Cass County/Province, ND, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

* [(b)(4) Foster County/Province, ND, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-170XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[(b)(4) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ND, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

[(b)(4)
(b)(4) Foster County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ND, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

[(b)(4) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ND, USA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

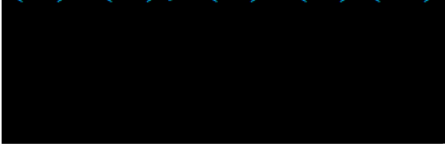
Monsanto Reference ID

2000-170XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005644

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agravo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-170XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 22, 2000

00-054-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-170XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-170XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:
KS, ND

DESTINATION:
KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Foster County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-170XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005655

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-170XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

February 22, 2000

00-054-06n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-170XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Cheserfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana ~~EPSPS~~ gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana ~~EPSPS~~ gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* ~~CTP2~~ ~~CTP6~~ gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, ND

DESTINATION:

KS, ND

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-170XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Foster County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

MONSANTO

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CBI-DELETED

Monsanto Reference ID

2000-170XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE: (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005663

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-054-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-06n	Applicant #:	2000-170XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005664

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-054-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-06n	Applicant #:	2000-170XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005665



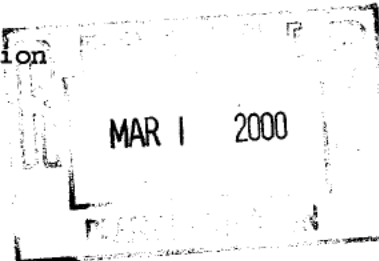
United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000



Dear Mr. Sim IV:

Enclosed is notification 00-054-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-06n	Applicant #:	2000-170XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

state acknowledges receipt of
this notification but

~~State DOES NOT CONCUR and offers the following reasons:~~

cannot evaluate.

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 3/8/00

State: Kansas

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005666

MAR 15 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 24, 2000

Dear Mr. Nelson:

Enclosed is notification 00-054-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-054-06n
Received: February 23, 2000
Institution: Monsanto
Interstate destination: KS ND
Release destination: ND

Applicant #: 2000-170XRAB
Effective: March 24, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

S. Dianne Ratmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature: (b) (6), (b) (7)(C)

Date: 3-9-2000

State: ND

Rptloc01/R4

MAR 10 2000



APHIS - Protecting American Agriculture

OR120018_BR_005667

P. 460 NO. 460

ND AG DEPT

MAR. 9. 2000 4:19PM

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-06n (2000-170XRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-054-06n

OR120018_BR_005668

Confirmation Report-Memory Send

Time : Mar-21-00 03:50pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 213
Date : Mar-21 03:36pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 03:47pm
End time : Mar-21 03:49pm
Pages sent : 01
Job number : 213

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-06n (2000-170XCRAB)
Regulated article - Wheat
Destinations - Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Katmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_005669

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

April 20, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms Hatmaker;

In reviewing Monsanto's acknowledged wheat notification, it was discovered an incorrect release site was given. USDA number 00-054-06n, Monsanto number 2000-170XRAB, the corrected site should be North Dakota State University at 0.25 mile west of intersection 18th and 19th Avenue, Fargo, North Dakota.

I apologize for any inconvenience this may cause. Please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc: D. Nelson, North Dakota Department of Agriculture
R. Stokes, Regional Biotechnologist, Sacramento, CA

OR120018_BR_005670

MONSANTO

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

April 20, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Not A FOIA Deletion

Dear Ms Hatmaker;

In reviewing Monsanto's acknowledged wheat notification, it was discovered an incorrect release site was given. USDA [REDACTED] Monsanto number 2000-170XRAB, the corrected site should be North Dakota State University at 0.25 mile west of intersection 18th and 19th Avenue, Fargo, North Dakota.

I apologize for any inconvenience this may cause. Please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc: D. Nelson, North Dakota Department of Agriculture
R. Stokes, Regional Biotechnologist, Sacramento, CA

OR120018_BR_005671

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

July 25, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

The following wheat sites for release have been canceled.

USDA # 00-040-09n, Monsanto # 2000-97XRAB

(b) (6), (b) (7)(C), (b) (4)

Heppner Morrow County, OR

(b) (4)

Lincoln County, OR

USDA # 00-059-03n, Monsanto # 2000-182XRAB

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Thompson County, (b) (6), (b) (7)(C), (b) (4) ND

(b) (6), (b) (7)(C), (b) (4) Trail County ND

USDA # 00-054-06n, Monsanto # 2000-170XRAB

(b) (4)

(b) (4) Cass County ND

USDA # 00-054-09n, Monsanto # 2000-174XRAB

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Galletin County, MT

USDA # 00-059-07n, Monsanto # 2000-188XRAB

(b) (4)

(b) (4)

(b) (4) Minndoka County, ID

(b) (4) Canyon County ID

If you need further information, please contact me at (b) (6), (b) (7)(C)

OR120018_BR_005672

apb
7/27/00

MONSANTO

Food • Health • Hope



Sincerely,

(b) (6), (b) (7)(C)

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

cc J. Griesbach, Oregon Dept. of Agriculture, Salem, OR
D. Nelson, North Dakota Dept. of Agriculture, Bismarck, ND
E. Gingerly, Montana Dept. of Agriculture, Helena, MT
F. Vega, Idaho Dept. of Agriculture, Boise, ID
R. Stoaks, USDA, APHIS, Sacramento, CA

OR120018_BR_005673

CONFIDENTIAL

**2000 Wheat Field Test Report
USDA #00-054-06n Monsanto #2000-170XRAB**

August 30, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147303528	Cass County	ND
2147303530	Foster County	ND
2147303527	Cass County	ND

Cass County/ND (2147303528)

(b) (4)

(b) (4)

Foster County/ND (2147303530)

(b) (4)

(b) (4)

Cass County/ND (2147303527)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2000 Wheat Field Test Report
USDA #00-054-06n Monsanto #2000-170XRAB**

August 30, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147303528	Cass County	ND
2147303530	Foster County	ND
2147303527	Cass County	ND

Cass County/ND (2147303528)

Planting Date: 05/03/2000

Harvest Date: 08/19/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Foster County/ND (2147303530)

Planting Date: 05/08/2000

Harvest Date: 08/18/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Cass County/ND (2147303527)

Planting Date: 04/27/2000

Harvest Date: 08/19/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Planting Date: 04/27/2000

Destruct Date: 07/28/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

2/24/00 12:58 pm

Notification Tracking Sheet

=====
Bp number: 00-054-07n
=====

App number: 2000-171XRAB
Received: 2/23/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/24/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085
=====

- | | Initial | Date |
|--|----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [aip] | [2/24/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZ] * | [2/28/00] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KZ] | [2/29/00] * |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Release	* *ID	*	1*WR *

- | | | |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [aip] | [2/28/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZ] | [3/20/00] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZ] | [3/22/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-171XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 22, 2000

00-054-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-171XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3'

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:
ID, MO

DESTINATION:
ID, MO

Ship From:

ID

(b) (4)

Cassia County/Province, ID, USA

CONTACT:
USA

(b) (4), (b) (6), (b) (7)(C)

ID, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Twin Falls County/Province, ID, (b) (4) USA

CONTACT:
USA

(b) (4), (b) (6), (b) (7)(C)

ID, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

(b) (4)

U.S.A. St. Louis County/Province, MO (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

Ship To:

ID

* (b) (4) Cassia County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Twin Falls County/Province, ID (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-171XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

(b) (4)

Cassia County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63108

PHONE (314) 694-1000

<http://www.monsanto.com>


Monsanto Reference ID

2000-171XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005695

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-171XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-171XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

Ship To:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

[CBI Deleted] -- Cassia County/Province, ID, USA, 5 acres

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-171XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005710

MONSANTO

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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
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Monsanto Reference ID

2000-171XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-171XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene **fusion** composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* **EPSPS** gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

ID, MO

DESTINATION:

ID, MO

Ship From:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

Ship To:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2000-171XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

ID

[CBI Deleted] -- Cassia County/Province, ID, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

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PHONE: (314) 694-1000

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Monsanto Reference ID

2000-171XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005722

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 24, 2000

Dear Dr. Vega:

Enclosed is notification 00-054-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-07n	Applicant #:	2000-171XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005723

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-054-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-07n	Applicant #:	2000-171XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005724



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

MAR 01 2000

PLANT INDUSTRIES

February 24, 2000

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

Dear Dr. Vega:

Enclosed is notification 00-054-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-054-07n
Received: February 23, 2000
Institution: Monsanto
Interstate destination: ID MO
Release destination: ID

Applicant #: 2000-171XRAB
Effective: March 24, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: March 2, 2000

State: IDAHO

Rpt1loc01/R4

MAR 2 2000

OR120018_BR_005725

An Equal Opportunity Employer



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-054-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-07n	Applicant #:	2000-171XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3-14-00

State: MO

Rptloc01/R4

MAR 14 2000



APHIS - Protecting American Agriculture

OR120018_RR_005726

P.05/09 3147510005

DEPT OF AGRICULTURE

MAR-14-2000 15:22

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-07n (2000-171XRAB)
Regulated article - Wheat
Destinations - Idaho, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-054-07n

OR120018_BR_005727

Confirmation Report-Memory Send

Time : Mar-21-00 03:50pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 215
Date : Mar-21 03:44pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 03:47pm
End time : Mar-21 03:50pm
Pages sent : 01
Job number : 215

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-07n (2000-171)KRB
Regulated article - Wheat
Destinations - Idaho, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Harmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
R. Vega, Idaho Dept. of Agric., Boise, ID
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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OR120018_BR_005728

2000 Wheat Field Trial Report
USDA # 00-054-07n Monsanto # 2000-171XRAB

Biotech Field Compliance Team
June 12, 2001
Monsanto Company

Location
Site 1

County
Cassia

State
ID

Site 1

(b) (4)

Site 1

(b) (4)

(b) (4)

Site 1

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-054-07n Monsanto # 2000-171XRAB

Biotech Field Compliance Team
June 12, 2001
Monsanto Company

Location	County	State
Site 1	Cassia	ID

Site 1

Planting Date: April 13, 2000

Harvest Date: September 4, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Site 1

Planting Date: April 17, 2000

Destruct Date: July 28, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Site 1

Planting Date: April 17, 2000

Destruct Date: July 28, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]